

OCT 27 2008

2. 510(k) Summary

Date Summary Prepared: August 26, 2008

Applicant: Medtronic Neuromodulation
710 Medtronic Pkwy., N.E.
Minneapolis, MN 55432-5604

Contact: Jeanmarie Sales
Regulatory Affairs Director, Gastro/Uro
763-505-0256
763-505-0258 (fax)

Trade Name: TUNA Therapy Model 8929 Hand Piece
(branded as: PROSTIVA[®] RF Therapy Model 8929 Hand Piece)

Classification Name: 21 CFR 876.4300 (Endoscopic electrosurgical unit and accessories)

Name of Predicate Device: TUNA Therapy Model 8929 Hand Piece
(branded as: PROSTIVA[®] RF Therapy Model 8929 Hand Piece)

Device Description

The Medtronic TUNA (Transurethral Needle Ablation) Therapy is a minimally invasive treatment for patients with lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). Medtronic is commercializing the branded product as the PROSTIVA[®] RF Therapy System which uses precisely focused radio frequency (RF) energy to ablate prostate tissue. The Prostiva RF Therapy Model 8929 Hand Piece is the delivery system component of the Prostiva RF Therapy System.

Indications for Use

The TUNA System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cm³.

Performance Standards

No applicable mandatory performance standards or special controls exist for this device.

Substantial Equivalence

The results of the design verification testing indicate that the modified PROSTIVA RF Therapy Model 8929 Hand Piece with handle modifications is substantially equivalent to the currently marketed device. There are no changes in specifications or indications for use.

**Medtronic**

Confidential

Prostiva RF Model 8929 Hand Piece
Special 510(k) Change Being Effected

August 2008

Summary of Testing

Design verification testing was performed to support modifications to the TUNA Therapy Model 8929 Hand Piece device and the device met all design and performance requirements.

Conclusion

The modified device is substantially equivalent to the currently marketed PROSTIVA RF Therapy Model 8929 Hand Piece based upon design verification test results and the indications for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jeanmarie Sales
Regulatory Affairs Director, Gastro/Uro
Medtronic, Inc.
710 Medtronic Parkway, N.E.
MINNEAPOLIS MN 55432-5604

OCT 27 2008

Re: K082464
Trade/Device Name: PROSTIVA® RF Therapy Model 8929 Hand Piece
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Codes: KNS and GEI
Dated: August 26, 2008
Received: August 27, 2008

Dear Ms. Sales:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

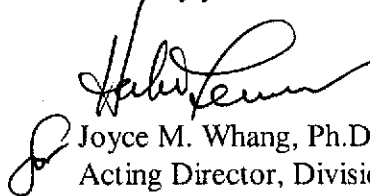
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Joyce M. Whang", is written over the typed name.

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K082464

Device Name: PROSTIVA® RF Therapy Model 8929 Hand Piece

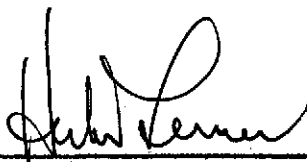
Indications for Use:

The TUNA System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cm³.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
Per 21 CFR 801.109



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K082464